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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,856	03/05/2001	Yat Sun Or	ENP019	5605

7590 12/31/2002

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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/31/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/800,856

Applicant(s)

OR ET AL.

Examiner

Samuel W Liu

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 and 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicants' election of Group I, Claims 1-4 and 8 in Paper No. 6 filed 4 November 2002 (Paper No. 6) and additional election of the subgroups "B" as α -amino butyric acid, "U" as α -(D) alanine, "X" as absent and "Y" as COOCH_3 with traverse are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Thus, Claims 1-4 and 8 are pending and examined in this Office action.

Specification/Claim Objections

The disclosure is objected to because of the following informalities:

In page 1, line 25, "COPD" should be spelled out in full for the first instance of use. See also, page 2, line 7, "NSAIDS"; page 23, line 7, "DMSO", page 24, line "HEPES", and page 24, line 29, "HBSS".

In page 14, line 9, "scarcosin" should be changed to "sarcosine".

In page 19, line 8, " $\text{Y}=\text{COOCH}_3$ " should be changed to " COOCH_3 "; and same change should be made throughout the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear as to whether or not "a pharmaceutically acceptable salt" refers to "U" or to the "cyclosporin". The dependent claims are also rejected.

Claim 2 is indefinite regarding lack of a period at the end of the claim recitation.

Claim 4 is indefinite for lack of punctuation ";" or "," between members of the Markush group and the absence of an "and" or, an "or" between the second to the last and the last recited member of the Markush group. An "and" or an "or" would appear to be necessary else the cyclosporin would be considered to have all compounds in the claim set forth.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang, N. Y. *et al.* (US Pat. No. 5239037).

Wang *et al.* disclose a cyclosporin structure that meets the limitations of the Formula (I) structure of claim 1 of the instant application (see patent column 8, formula III wherein "W" is 1

Art Unit: 1653

carbon atom, "Y" is Oxygen atom, "m" =0, and "Z" is OR_a [R_a =-CH₃]. Since Applicant elects "B" as -α-amino butyric acid, "U" as -(D) alanine, "X" as absent, and "Y" as COOCH₃ for patent examination, claims 2-4 are anticipated by the patent reference as well.

In addition, Wang *et al.* teach a carrier that is a poly(amino acid) or bovine serum albumin (see column 4, lines 24-29), as applied to claim 8 of the current application.

Provisional Rejection - Obviousness Type Double Patenting

Claims 1-4 and 8 of this application conflict with Claims 1-3 and 11 of Application No. 09976219. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 8 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-3 and 11 of copending Application No. 09976219. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claim 1 of Application 09976219 [see formula I (A1)] discloses the same subject matter as that of claim 1 of the instant application with respect to the generic structure of a cyclosporin analog.

Claims 2 and 3 of Application 09976219 set forth the limitations for claim 1 from which claims 2 and 3 depend, which are obvious variation of claims 2 and 3 of the current application.

Claim 4 of Application 09976219 sets forth the compound wherein $Y = (\text{SO})\text{Ph}$ is obvious structural variation of the compound wherein $Y = (4'\text{C}(\text{O})\text{SCH}_2)\text{Ph}$ of claim 4 of the current application.

Claim 11 Application 09976219 sets forth a pharmaceutical composition which is the same as that of claim 8 of the current application; though the scope of the claim is different, the subject matter of the claims of the reference application and the current application are the same, *i.e.*, the composition comprising a cyclosporin compound of claim 1 and a pharmaceutically acceptable carrier.

Therefore, the instant application and copending application claims are obvious variation.

Claims 1-4 and 8 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-3 and 11 of copending Application No. 09975923. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claim 1 of Application 09975923 [see formula I (A1)] discloses a cyclosporin variant that is an obvious structural variation of that set forth in the claim 1 [formula (1)] of the current application. In formula I of 09975923, moiety of "A" is an obvious structural variation over the moiety of "A" set forth in formula (1) of the present application in that, provided that "Y" is a functional group ("X" is absent), Application 09975923 discloses the same limitation for the moiety "Y" as that of the present application. Furthermore, because the specification of 09975923 does not set forth importance of type of chemical bond (the secondly adjacent to "X-

Y” linkage) or/and related configuration thereof, the “Y” moieties in the both the reference application and the current application are regarded as structural or functional variations each other.

Claims 2-4 of the Application 09975923 and claims 2-4 of the current application are the same disclosures.

Claim 9 of the Application 09975923 discloses the same subject matter as to a pharmaceutical composition as that of claim 8 of the current application, *i.e.*, the composition comprising a cyclosporin compound of claim 1 and a pharmaceutically acceptable carrier.

Therefore, the instant application and copending application claims are obvious variation.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Application/Control Number: 09/800,856
Art Unit: 1653

Page 8

Samuel Wei Liu
December 27, 2002


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